REMARKS

Claims 2, 10 and 11 have been amended in order to recite the present invention with the specificity required by statute. No new matter has been added.

Claim 10 is objected to for minor informalities. In response, claim 10 has been amended in conformity with the Examiner's kind suggestions.

Claim 2 is rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. In response, claim 2 is also amended in conformity with the Examiner's kind suggestions.

Claim 7 is rejected under 35 U.S.C. §101 because the claimed invention is not supported by specific and/or substantial utility, or well established utility. Although claim 7 recites a process for producing a protein of SEQ. ID NO. 2, the Examiner states the protein per se must have "a specific and/or substantial or well established utility." At the outset, this rejection is not well-understood. For instance, "the state of the prior art implies a well established utility of using the peptide to raise antibodies for using [sic] in assays." See, e.g., the PTO Training Materials for Examining Patent Applications With Respect to 35 U.S.C. §112, First Paragraph at page 0-3. This is plainly in conformity with the teachings of the specification (see the Office Action from page 3, line 18 to page 4, line 2). Although the Examiner states such is a "non-specific use that is applicable [sic] proteins in general and not particular or specific to the protein being claimed" that remark is off-point. If the asserted utility is substantial --as it is here-- it is plainly irrelevant that it such is non specific.

In any event, the Examiner's analysis ignores the fact that here the asserted

utility is specific, namely that the antibody can be used as a diagnostic or therapeutic agent. In this regard, the amino acid sequences of SEQ ID NO:2 would be considered by those of ordinary skill the protein encoded by the mRNA of SEQ ID NO:1 for at least the following reasons:

i) The amino acid sequence of SEQ ID NO:2 is encoded by the longest ORF among the ORF's of the sequence of SEQ ID NO:1. Accordingly, one of ordinary skill in the art would expect the OFR to be translated.[1/]

ii) As described at page 39, lines 14-20 in the specification, the amino acid sequence of SEQ ID NO:2 has a homology with the C end side of the pumilio protein having mRNA binding ability. The homologous portion is a motif, "pumilio-family RNA binding repeat", e.g., an RNA biding domain conserved in an RNA-binding proteins, such as pumilio and nematode FBF-1,2 in the protein domain data base, Pfam (Sonnhammer EL et al., *Nucleic Acids Res.*, *26*:320-322 (1998)). Consequently, the amino acid sequence is considered by those of ordinary skill to be an amino acid sequence of a protein having RNA binding ability (e.g., it is not a meaningless sequence).[2/]

As noted, a protein comprising the amino acid sequence of SEQ ID NO:2 is expected to be encoded by the mRNA of SEQ ID NO:1. Since protein is produced in a cell by translation from mRNA, one of ordinary skill in the art would consider that, as the amount of mRNA is increased in a cell, the amount of a protein encoded by the mRNA is

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1/ If necessary, Applicants will be happy to submit references or Expert Declarations supporting this statement.

2/ If necessary, Applicants will be happy to submit references or Expert Declarations supporting this statement.

increased. Accordingly, the amino acid sequence of SEQ ID NO:2 is an amino acid sequence of a protein encoded by a gene of which expression is increased in leukocyte of an IgA nephropathy patient. Accordingly, IgA nephropathy can be diagnosed by measuring the amount of the protein and comparing the measured amount with the amount of protein in a healthy person.

Claims 2, 5, 6, 8-11 and 23-28 are rejected under 35 U.S.C. §112, first paragraph, because the specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims. As understood, the bases of this rejection is the same as that concerning claim 7. Such rejection is therefore addressed by the foregoing remarks and by the cancellation of claims 23-28.

Claims 10, 11 and 25-28 are rejected under 35 U.S.C. §112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, claims 10 and 11 have been amended in conformity with the Examiner's kind suggestions. The rejection of claims 25-28 is mooted by their cancellation. Regarding claim 10, the Examiner further states that it recites two identical steps. However, in step 1 on oligonucleotide is selected from the sequence of Seq. ID NO. 1 and in step 2 an oligonucleotide is selected which is complementary to the sequence of SEQ ID NO. 1. Accordingly, the two steps are clearly different.

Claims 8 and 23 are rejected under 35 U.S.C. §102(b) as being anticipated by Matsubara. Claims 8 and 9 are rejected as anticipated by Hillier. Claims 24 and 28 are rejected as anticipated by Hillier (Assession No. N21024) and Claims 25 and 27 are

rejected as anticipated by Hillier (Assession numbers T55131 and T46955, see alignments mailed with the prior Office Action, mailed August 16, 2000). This rejection is mooted by the cancellation of these claims.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 2-7, 10 and 11 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should be directed to our below listed address.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE TO CLAIMS

2. (Three Times Amended) An isolated DNA encoding a protein comprising the amino acid sequence represented by SEQ ID NO: 2.

Claim 8 (Cancelled).

Claim 9 (Cancelled).

10. (Three Times Amended) A diagnostic method for detecting an IgA nephropathy in a patient, comprising:

selecting an oligonucleotide comprising 15 mer portion of the nucleotide sequence of DNA selected from the group consisting of DNA encoding a protein comprising the amino acid sequence represented by SEQ ID NO: 2, DNA comprising the nucleotide sequence represented by SEQ ID NO: 1, and DNA which hybridizes with the nucleotide sequence represented by SEQ ID NO: 1 under stringent conditions;

selecting an [olignucleotide] oligonucleotide comprising a 15 mer portion of a nucleotide sequence complementary to DNA selected from the group consisting of DNA encoding a protein comprising the amino acid sequence represented by

SEQ ID NO: 2, DNA comprising the nucleotide sequence represented by SEQ ID NO: 1, and DNA which hybridizes with the nucleotide sequence represented by SEQ ID NO: 1 under stringent conditions; [and]

using said oligonuleotides in a reverse-transcription-polymerase chain reaction to detect mRNA corresponding to the nucleotide sequence represented by SEQ ID NO:1; and

determining an IgA in said patient based on a result of said reverse-transcription-polymerase claim reaction.

11. (Three Time Amended) A diagnostic method for detecting an IgA nephropathy in a patient, comprising:

selecting an oligonucleotide comprising a 15 mer portion of a nucleotide sequence complementary to DNA selected from the group consisting of DNA encoding a protein comprising the amino acid sequence represented by SEQ ID NO: 2, DNA comprising the nucleotide sequence represented by SEQ ID NO: 1, and DNA which hybridizes with the nucleotide sequence represented by SEQ ID NO: 1 under stringent conditions; [and]

using said olignucleotide in a Northern blot to detect mRNA corresponding to the nucleotide sequence represented by SEQ ID NO: 1; and

determining an IgA nephropathy in said patient based on a result of said Northern blot.

Claim 23 (Cancelled).

Claim 24 (Cancelled).

Claim 25 (Cancelled).

Claim 26 (Cancelled).

Claim 27 (Cancelled).

Claim 28 (Cancelled).